

1 REMARKS

2 Status of the Claims

3 Claims 1, 2, 4-11, 14, 15, 17- 41, 43-45, 48-61, 74, 76-81 and 88-100 remain pending in the
4 present application. Claims 3, 12, 13, 16, 42, 46, 47, 62-73, 75 and 82-87 having been previously
5 canceled, and Claims 1, 2, 4, 5, 6, 55, 57, 91, and 96-99 have been amended to more clearly define
6 the recited subject matter.

7 Claims Rejected Under 35 U.S.C. § 102(b) over Adams

8 Claims 2, 7, 9, 15, 20-28, 35-37, 45, 48-50, 53-61, 74, 76, 77, 88-90, and 97-98 have been
9 rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,134,218 (Adams et al. -
10 hereinafter referred to as "Adams"). Applicant respectfully disagrees with the above rejections for at
11 least the following reasons.

12 In the interest of reducing the complexity of the issues for the Examiner to consider in this
13 response, the following discussion focuses on independent Claims 1, 2, 45, 55, 57, 74, 79, 88-91,
14 and 95-100. Please note that although the patentability of at least one dependent claim is discussed, the
15 patentability of each remaining dependent claim is not necessarily separately addressed in detail.
16 However, applicant's decision not to discuss the differences between the cited art and each dependent
17 claim should not be considered as an admission that applicant concurs with the Examiner's conclusion
18 that these dependent claims are not patentable over the disclosure in the cited references. Similarly,
19 applicant's decision not to discuss differences between the prior art and every claim element, or every
20 comment made by the Examiner, should not be considered as an admission that applicant concurs with
21 the Examiner's interpretation and assertions regarding those claims. Indeed, applicant believes that all
22 of the dependent claims patentably distinguish over the references cited. In any event, a specific
23 traverse of the rejection of each dependent claim is not required, since dependent claims are patentable
24 for at least the same reasons as the independent claims from which the dependent claims ultimately
25 depend.

26 Patentability of Independent Claim 2

27 Claim 2 has been amended to clarify that the conductive elastomer is not based on
28 incorporating a metal foil into a polymer matrix. Applicant disclosed several different techniques for
29 generating conductive elastomers, including the use of naturally conductive polymers, distributing
30 conductive carbon in a polymer matrix, distributing metal powders in a polymer matrix, and using

1 metal foil. Applicant specifically noted that the metal foil embodiment did not exhibit a self healing
2 capability exhibited by the other disclosed conductive elastomers (this topic is discussed at page 61 of
3 applicant's specification).

4 Adams does not recognize the benefit of this self-healing ability. Further, modifying Adams
5 to incorporate such a self-healing property would provide no benefit, as the principle of operation of
6 Adams is based on detecting pressure changes to determine that a user is correctly examining
7 simulated breast tissue. The use of a self-healing conductive elastomer able to withstand repeated
8 punctures (such as by a syringe) is irrelevant to Adams functionality, and any modification of Adams
9 to include such a conductive elastomer would impermissibly rely on hindsight.

10 Accordingly, the rejection of independent Claim 2 under 35 U.S.C. § 102(b) should be
11 withdrawn.

12 Since dependent claims inherently include all of the recitation of the independent claims from
13 which they ultimately depend, for at least the same reasons as noted above in connection with
14 independent Claim 2, the rejection of dependent Claims 7, 9, 15, 20-28, 31, and 35-37 should also be
15 withdrawn.

16 Patentability of Independent Claim 45

17 Claim 45 requires that first and second conductive segments are placed in **physical contact**
18 with each other during a simulated medical procedure. Adams discloses first and second conductive
19 elements that are separated by a pressure conductive polymer that is a resistor at rest, and a conductor
20 when pressure is applied. Regardless of whether pressure is applied or not, the two conductive
21 segments are always physically separated by the pressure conductive polymer, and are never in
22 physical contact.

23 The Examiner asserts that during applied pressure the resistance of the pressure conductive
24 polymer drops to as low as 0.1 ohms, and thus effectively eliminates the non-conductive gap.
25 Applicants respectfully submit that simply because the conductivity of the pressure conductive
26 polymer changes does not mean that the pressure conductive polymer is no longer separating the two
27 portions of the conductive elastomer evaluation circuit.

28 In Adams' model, a plurality of flexible electrically conductive strips 50 (best seen in FIG. 4)
29 are adjacent to pressure conductive polymer layer 48 and are arranged substantially perpendicular to
30 strips 46 (column 7, lines 4-7). Significantly, the pressure conductive polymer separates strips 46 and

50. Adams' principle of operation is that the application of pressure causes the resistance of the pressure conductive polymer to decrease, and when resistance decreases, electrical conductance increases so that there is **an electrical connection** between strips 46 and strips 50 at the location where pressure is applied (column 7, line 65-column 8, line 3). Significantly, the perpendicular conductive strips are always separated by the pressure conductive polymer layer. Clearly, the perpendicular conductive strips are never physically connected, although changes in the pressure conductive polymer layer electrically couple the perpendicular conductive strips.

Significantly, the principles of operation between the device of Claim 45 and Adams are different. In Adams' device, the conductors are not separated by a gap, there is a physical layer separating the conductors, and changes in the electrical properties of that physical layer control whether a current flows from one conductor to another. To achieve an equivalent, the principle of operation of Adams would need to be changed to eliminate the pressure conductive polymer layer and instead rely on a physical gap and motion of the conductors to close that gap. Such a modification violates MPEP 2143.01, which specifically provides that "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."

Accordingly, the rejection of independent Claim 45 under 35 U.S.C. § 102(b) should be withdrawn, because Adams does not teach or suggest placing conductive segments in physical contact with one another.

Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 45, the rejection of dependent Claims 48-50 and 53-54 should also be withdrawn.

Patentability of Independent Claim 55

Claim 55 has been substantially amended, and currently recites that the evaluation circuit is configured to provide data via an electrical signal originating from the portion of the simulated physiological structure in response to at least one of the following conditions:

(a) a manipulation of the portion of the simulated physiological structure causes the conductive path of the evaluation circuit to be opened; and

(b) an instrument is placed in proximity to at least a portion of the simulated physiological structure, but not in contact with any portion of the evaluation circuit, the instrument not being configured to introduce an electrical current into the evaluation circuit.

Significantly, Claim 55 no longer recites detecting a change in a non-electrical property, thus the rejection based on Adams no longer applies.

With respect to Hamilton, note that the claim language defines the conductive path to be part of the simulated physiological structure, and requires that the part of the circuit that opens/closes is incorporated into the simulated physiological structure. As discussed in detail below with respect to the obviousness rejection of Claim 1, Hamilton discloses a training model wherein the part of the circuit that opens and closes is in a support base, not the simulated physiological structure.

Accordingly, the rejection of independent Claim 55 under 35 U.S.C. § 102(b) should be withdrawn.

Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 55, the rejection of dependent Claim 56 should also be withdrawn.

Patentability of Independent Claim 57

Claim 57 has been amended to include the elements recited in Claim 2 as amended, and thus distinguishes over the cited art for the same reasons.

Accordingly, the rejection of independent Claim 57 under 35 U.S.C. § 102(b) should be withdrawn.

Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 57, the rejection of dependent Claims 58-61 should also be withdrawn.

Patentability of Independent Claim 74

Claim 74 recites a method in which a user of a training model can control how a signal from an evaluation circuit is employed. The user can control the model such that the signal directs an indication of the performance to the user, to another party, or to an electronic storage location, as recited in step (c).

Adams teaches that a trainee is enabled to make a positive indication if he detects a simulated tumor or to make a negative indication if he does not detect a simulated tumor (column 9, lines 13-

17). In addition, the trainee may activate switches relating to the detection of tumor size or other variables (column 9, lines 36-39). Furthermore, Adams teaches that a computer determines whether the positive or negative detections are correct and that the computer may provide signals on a display to the trainee (column 9, lines 26-33). But there is no teaching that a user can choose how a signal from the evaluation circuit is used, based on three different choices. While Adams enables a user to make selections, those selections are not equivalent.

Accordingly, the rejection of independent Claim 74 under 35 U.S.C. § 102(b) should be withdrawn.

Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 74, the rejection of dependent Claims 76 and 77 should also be withdrawn.

Patentability of Independent Claim 88

Significant differences exist between the recited subject matter and the cited art because the cited art does not teach or suggest the removal of a non conductive segment.

The Examiner appears to be arguing that changing the electrical properties of a layer separating conductive portions of a circuit is equivalent to physically removing the layer that separates the conductive portions. Respectfully, that is logically incorrect. Adams employs an entirely different principal of operation. In Adams' apparatus, element C (the pressure sensitive conductive polymer) always separates elements A and B (the conductors). Applicant's principle of operation is removing element C (a non-conductive material) and physically attaching element A (a first conductor) to element B (a second conductor).

There is no teaching of actually removing the polymer in Adams, thus this claim distinguishes over Adams. Further, as noted above, MPEP 2143.01 does not allow the principle of operation of a cited reference to be modified in order to achieve an equivalent to the recited subject matter. Accordingly, the rejection of independent Claim 88 under 35 U.S.C. § 102(b) should be withdrawn.

Patentability of Independent Claim 89

Claim 89 specifically recites that a simulated medical procedure repositions conductive segments such that they are placed in physical contact with one another (not merely electrically connected), thereby completing the circuit.

1 Adams discloses a device wherein a layer physically separates two conductors, and that layer
2 is non-conductive in the absence of pressure, and conductive when a pressure is applied. It is simply
3 incontrovertible that the conductors disclosed by Adams are physically separated by this layer, and
4 that the conductors separated by this layer never physically contact one another, as required in
5 applicant's claim.

6 Accordingly, the rejection of independent Claim 89 under 35 U.S.C. § 102(b) should be
7 withdrawn.

8 Patentability of Independent Claim 90

9 Claim 90 specifically recites a method for using a medical trainer, where the medical trainer
10 includes:

11 a non-target area representing a portion of the simulated physiological structure that can be
12 undesirably damaged if the simulated medical procedure is performed improperly, that portion
13 comprising a conductive elastomer based evaluation circuit, the evaluation circuit being configured to
14 provide a signal relating to a simulated procedure being performed on the simulated physiological
15 structure, the signal being provided when that portion is improperly accessed during a simulated
16 medical procedure

17 Adams discloses a medical trainer that includes an evaluation circuit that is present
18 throughout the breast model, so that any portion of the breast model manipulated by a student is
19 detected. Some portions of the breast model include tumors, and other portions do not. Analyzing
20 the signals from the evaluation circuit enables a determination to be made pertaining to correct and
21 incorrect performance of a breast exam. Thus, Adams does encompass determining if a non-tumor
22 containing portion of the model was examined.

23 However, applicant respectfully submits that essentially the entire breast model is a target
24 portion. In other words, Adams' breast model simply does not include any portion that is a non target
25 portion. Consider that a breast tumor can be located anywhere on a breast. Thus, breast exams check
26 each portion of the breast for suspect lumps. With respect to Adams' breast model, the portions of
27 the model including a simulated tumor are particularly important, but still, even portions where
28 tumors are not present need to be examined.

29 In contrast, Claim 90 describes a medical model that includes portions that can be damaged if
30 manipulated during a procedure. For example, a blood vessel near a simulated physiological

1 structure that is to be manipulated can represent a non-target portion that could be damaged. The
2 method of Claim 90 is configured to determine whether or not a student accesses a portion of the
3 model representing an area that would be undesirably damaged during a simulated procedure.

4 Significantly, the model disclosed by Adams does not include portions that could be damaged
5 if a breast exam were performed incorrectly. Further, Adams does not teach an evaluation circuit that
6 generates an indication when a portion of the structure that can be undesirably damaged by an
7 improperly performed procedure is accessed during a simulated procedure. Accordingly, the
8 rejection of independent Claim 90 under 35 U.S.C. § 102(b) should be withdrawn.

9 Patentability of Independent Claim 97

10 As amended, Claim 97 recites that a gap between the first and second conductive segments is
11 eliminated without applying pressure to an external surface of the simulated physiological structure.

12 Applicant respectfully submits that the Examiner has incorrectly asserted that the change in
13 the electrical conductivity of Adams' pressure sensitive conductive polymer is equivalent to
14 elimination of a separation between two conductive elements. Adams teaches that the properties of a
15 material separating two conductors changes in response to an applied pressure. There is no gap
16 disclosed by Adams, and logically the gap that does not exist cannot be eliminated.

17 Further, applicant has amended Claim 97 to indicate that the gap (which does not even exist in
18 Adams' model) is eliminated via some process other than applying pressure. Applicant's
19 specification includes embodiments that eliminate gaps such as by reconnecting the adjacent ends of
20 the blood vessel, such that the circuit is completed and the circuit provides an indication that the
21 procedure was performed correctly (applicant's specification, page 36, lines 8-10), or where a break
22 in the epidermal layer is sealed by suturing together a simulated wound, (applicant's specification,
23 page 36, lines 14-15), or by coupling together a simulated broken bone (applicant's specification,
24 page 36, lines 15-16). None of these embodiments eliminate gaps by applying pressure externally to
25 the simulated physiological structure.

26 Accordingly, the rejection of independent Claim 97 under 35 U.S.C. § 102(b) should be
27 withdrawn.
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1 Patentability of Independent Claim 98

2 Claim 98 as amended recites a conductive elastomer comprising a conductive powder
3 dispersed in an elastomeric matrix. Applicant's disclosure clearly discloses using conductive carbon
4 and metal powders added to a polymer to generate a conductive elastomer.

5 Adams does not teach or suggest an equivalent. Accordingly, the rejection of independent
6 Claim 98 under 35 U.S.C. § 102(b) should be withdrawn.

7 Claims Rejected Under 35 U.S.C. § 102(b) over Nicholls

8 Claims 91 and 95 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S.
9 patent publication 2003/0068606 (Nicholls et al.– hereinafter referred to as “Nicholls”). Applicant
10 respectfully disagrees with the above rejections for at least the following reasons.

11 Patentability of Independent Claim 91

12 Claim 91 as amended defines a medical trainer including three elements: an outer surface, a
13 first **planar** conductive elastomer evaluation circuit, and a second **planar** conductive elastomer
14 evaluation circuit, where the two circuits are substantially parallel to the outer surface
15 (FIGURES 14A, 14B, and 15, and the corresponding text in applicant's specification as filed disclose
16 planar conductive elastomer evaluation circuits).

17 In describing how conductive elastomer evaluation circuits are employed in the medical
18 simulator disclosed by Nicholls, the term layer is employed. Absent another further description, one
19 might argue that the term layer implies a generally planar form factor. However, Nicholls does
20 provide further context for the term layer, and it is clear that Nicholls does not use the term layer to
21 refer to generally planar form factors, but rather concentric circles. The relevant portions of Nicholls'
22 disclosure (paragraphs 13, 14, 25 and 27) are reproduced below.

23 [0013] In general the instrument may be a needle, a scalpel, a trocar, a cannula, or a catheter,
24 or any other medical instrument capable of penetrating the mannequin without destroying it. The
25 simulation of the part of the human anatomy may include a **replaceable simulated skin outer cover**
26 **comprising a conductive elastomer**, replaceable simulated muscle segments and a **replaceable**
27 **conductive elastomer element containing simulated nerves of conductive elastomer**. Different
28 thickness and characteristics of each of the elastomer elements (skin, muscle, nerves) may be
29 provided so that the user can experience different degrees of difficulty in palpating and penetrating
30 the anatomy proximal to the nerve. The simulation of the part of the human anatomy may also

1 include a simulated circulatory system and elements such as an artery or vein, which may contain
2 fluid.

3 Significantly, in paragraph 13 Nicholls defines a structure including two different conductive
4 elastomer evaluation circuits; the outer simulated skin and simulated nerves. Note the structure
5 defined in applicant's Claim 91 includes an outer layer, which need not be a conductive elastomer,
6 and requires that the model include conductive elastomer evaluation circuits that are planar.
7 Paragraph 13 provides absolutely no description of any planar conductive elastomer evaluation
8 circuit that is parallel to the outer layer. Applicant respectfully submits that it is illogical to assert
9 that a simulated nerve is planar.

10 [0014] The simulation of the nerve preferably includes a plurality of alternating conductive
11 and insulating **layers**. The sensor means preferably comprises a network of electrical contacts at
12 each conductive layer or element. Electrical contact with each of these independent layers by means
13 of an electrically charged needle or implement will complete an electrical circuit so that needle
14 location can be evaluated. Measurement of various electrical characteristics (e.g., resistance or
15 capacitance) within the conductive layer can be used to provide additional information (e.g., relative
16 position of contact within the layer or electrical current flow within the layer).

17 The layer language of paragraph 14 certainly provides a mental image of planar layers of a
18 conductive elastomer evaluation circuit. However, paragraph 14 cannot be considered independently
19 of the balance of Nicholls' disclosure. When paragraph 14 is analyzed along with FIGURES 2 and 3
20 and paragraphs 25 and 27, the meaning of Nicholls' use of the term layer becomes clear. Nicholls is
21 not disclosing planar layers of conductive elastomer evaluation circuits, rather Nicholls is disclosing
22 concentric layers of conductive elastomer evaluation circuits. Concentric layers and planar layers are
23 not equivalent.

24 [0025] Details of the nerves and artery of one particular embodiment, and the relative
25 positions of the conductive and non-conductive layers within the nerve segment 6 illustrated in
26 FIG. 1 are further shown in FIG. 2. The nerves 10 contained within the nerve segment 11 illustrated
27 in FIG. 2 are formed such that there are numerous concentric, penetrable conductive 12 and non-
28 conductive 13 layers. Each **concentric conductive layer 12** has an attached or molded electrical
29 contact 14. The electrical contacts 14 are connected to the simulator base 21 and allow the electrical
30 signals to pass from the conductive layers 12 to the sensor interface. The arteries 15 are tubular,

penetrable and expandable. They are further designed to allow the passage of fluid to simulate blood flow and an arterial pulse. The arteries 15 also have a hydraulic connector 16 at each end.

[0027] As illustrated in FIG. 3 each of the conductive anatomical layers 12 is penetrable and is separated by at least one non-conductive penetrable layer 13. Detection of penetration relies on electrical current flow from the penetrating instrument, i.e., needle 17, to an electrical contact through the specific layer in which the tip of the needle is present. Only the needle tip 18 is conductive. Therefore, a specific layer 12 can be identified as being solely in contact with the needle and hence the needle location within the anatomical layers determined. The electrical current is provided by an external nerve stimulator attached to the needle or by an electrical potential provided by the sensor mechanism or outer conductive layer. The conductive and non-conductive layers that make up a simulated nerve can be formed such that they occur every few microns, providing needle detection in terms of depth to a few microns.

Nicholls simply does not teach or suggest applicant's planar layers of conductive elastomer evaluation circuits. Accordingly, the rejection of independent Claim 91 under 35 U.S.C. § 102(b) should be withdrawn.

Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 91, the rejection of dependent Claims 92-94 should also be withdrawn.

Patentability of Independent Claim 95

Claim 95 is generally similar to Claim 91, but Claim 95 defines the parallel conductive elastomer evaluation circuits as being two dimensional, rather than being planar. However, Nicholls discloses only a single two-dimensional conductive elastomer evaluation circuit, combined with a three-dimensional conductive elastomer evaluation circuit.

As discussed above, Nicholls discloses two types of conductive elastomer evaluation circuits; an outer skin layer/cover, and an inner nerve. Clearly, the outer skin layer is two-dimensional. However, it must be recognized that the structure of the conductive elastomer evaluation circuit simulating a nerve is three-dimensional (with a circular cross section). Nicholls' nerve is a tubular structure including concentric layers of conductors and insulators. Clearly, tubes are three-dimensional shapes, not two-dimensional shapes. Note that while FIGURES 2 and 3 only show the circular cross section of these tubes, it is illogical to assert that the concentric layers do not extend

1 into a third dimension (i.e., through the mass of the simulated tissue). Such an embodiment would
2 have little use as a training tool, as the student would need to insert a needle/simulated tool along the
3 edge of the simulated tissue mass shown in FIGURES 2 and 3, and Nicholls does not describe such a
4 procedure at all.

5 Nicholls simply does not teach or suggest applicant's inner two dimensional layers of
6 conductive elastomer evaluation circuits. Accordingly, the rejection of independent Claim 95 under
7 35 U.S.C. § 102(b) should be withdrawn.

8 Claims Rejected Under 35 U.S.C. § 103(a)

9 Claims 1, 38-41, and 96 have been rejected under 35 U.S.C. § 103(a) as being unpatentable
10 over U.S. Patent No. 4,872,841 (Hamilton et al. - hereinafter referred to as "Hamilton") in view of
11 Adams.

12 Claims 8, 10, 51, 52, and 99 have been rejected under 35 U.S.C. § 103(a) as being
13 unpatentable over Adams in view of U.S. Patent No. 5,589,639 (D'Antonio et al. - hereinafter
14 referred to as "D'Antonio").

15 Claims 29, 30, 32-34, and 78 have been rejected under 35 U.S.C. § 103(a) as being
16 unpatentable over Adams in view of U.S. Patent No. 5,853,292 (Eggert et al. - hereinafter referred to
17 as "Eggert").

18 Claims 43 and 44 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over
19 Adams in view of Nicholls.

20 Claims 79-81 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over
21 Hamilton in view of Adams and further in view of U.S. Patent No. 6,857,878 (Beach et al. -
22 hereinafter referred to as "Beach").

23 Claims 92-94 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over
24 Nicholls in view of U.S. Patent No. 6,857,878 (Pugh).

25 Claim 100 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Adams in
26 view of U.S. Patent No. 6,544,041 (Damadian).

27 Patentability of Independent Claim 1

28 Claim 1 specifically recites the portion of the evaluation circuit that opens is inside of the
29 simulated physiological structure. Note the following language:

manipulation of said portion of the simulated physiological structure causes the conductive path through the segment of the evaluation circuit that is configured as a portion of the simulated physiological structure to be opened

Clearly, the language of Claim 1 requires that a change in the conductive path within the simulated physiological structure occur due to manipulation of the simulated physiological structure (that change being a change from a close conductive path to an open conductive path).

The Examiner has noted that Hamilton discloses a medical training system which requires proper placement of elements in order to open particular sensory circuits and close other circuits; citing to column 2, lines 8-25 of the reference. The Examiner admits that Hamilton does not teach the use of conductive elastomers, but notes that the use of conductive elastomers in medical training models is taught by Adams. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to seek to improve the device of Hamilton by incorporating the use of conductive elastomers as taught by Adams, as such a modification represents updating the system of Hamilton with currently available technology.

Applicant respectfully disagrees for two reasons. First, the combination does not appear to be logical, and second, even when the references are combined, the portion of the circuit being opened would not be part of the simulated physiological structure (i.e., Hamilton's spine).

With respect to the first reason, the function of a conductive elastomer in a medical model is to enhance realism, because conductive elastomers can be configured to look and feel more realistic than can conventional metal wire conductors. Hamilton's model is a portion of the spine with lights embedded in the spine. Clearly, Hamilton's model is not intended to look or feel realistic. Hamilton's principle of operation is to use lights (more specifically, a pattern of blinking lights) embedded in a simulated physiological structure (a spine) in entirely non-realistic fashion (to indicate normal and abnormal nerve function. There would be no benefit to the modification proposed by the Examiner, because the level of realism that can be achieved using conductive elastomer evaluation circuits simply would provide no benefit to Hamilton's training model (in other words, the functionality of Hamilton's model would not be enhanced with conductive elastomer evaluation circuits). Thus, the modification proposed by the Examiner is based on hindsight, rather than a realistic combination of technologies to achieve an improvement.

1 It should be noted that the MPEP clearly recognizes that some logical benefit must be
2 achieved when references are combined. MPEP 2143.01 specifically provides that "if the proposed
3 modification or combination of the prior art would change the principle of operation of the prior art
4 invention being modified, then the teachings of the references are not sufficient to render the claims
5 prima facie obvious." As noted above, Hamilton's principle of operation is to embed lights in a
6 simulated physiological structure in a non realistic fashion to highlight nerve function. Adams
7 principle of operation is to use a conductive elastomer in a medical model to enhance realism. In
8 short, Hamilton does not emphasize realism, while Adams does, and those principles are mutually
9 contradictory.

10 With respect to the applicant's point that even when combined the reference fail to achieve an
11 equivalent structure, note that the portion of the opening in Hamilton's circuit is in the model's base,
12 not in the spine (the simulated physiological structure). Hamilton teaches two embodiments, but
13 neither embodiment includes a conductive path that is part of the simulated physiological structure
14 that is opened. Hamilton's first embodiment is illustrated in FIGURE 1 and FIGURES 3A-3B.
15 Significantly, in that first embodiment the portion of the circuit that is opened (i.e., switch SW2) is in
16 hollow display base 12. Hamilton's FIGURE 4, which is a schematic of the circuit for the first
17 embodiment, clearly shows an open circuit (as illustrated by the arrow), proximate near the label
18 'SW2'. As described by Hamilton, when second upper member 26 is moved out of alignment with
19 the first lower member 20 (column 3, lines 60-64) switch means SW2 is shifted to include resistor R6
20 in the circuit. Clearly, the portion of the circuit that changes from closed to open is not in the spine,
21 but in the base (i.e., switch SW2).

22 Hamilton's second embodiment discloses that appropriate circuit means may be mounted in
23 one of the bone-like members (column 4, lines 66-68), as opposed to a suitable display base.
24 However, in this embodiment, the circuit being opened and closed is not electrical, but optical.
25 Hamilton clearly teaches that when the members are misaligned an optical circuit is broken
26 (column 5, lines 6-11). Applicant respectfully submits that altering an optical circuit is NOT the
27 same as causing a conductive path to be opened. Therefore, applicant submits that neither of
28 Hamilton's embodiments reads on the recited claim language.
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1 Accordingly, the rejection of independent Claim 1 under 35 U.S.C. § 103(a) should be
2 withdrawn, because the references should not be logically combined, and even when combined the
3 references do not teach or suggest all of the elements of Claim 1.

4 Patentability of Independent Claim 79

5 Claim 79 recites a training model in which a conductive elastomer evaluation circuit has been
6 incorporated into a simulated joint or bone, and a processor employs data from the evaluation circuit
7 to assign a student a score based on the performance of a simulated procedure.

8 The Examiner has asserted that Hamilton discloses a medical training model including a
9 simulated bone, that Adams discloses a medical training model including a conductive elastomer
10 evaluation circuit, and that scoring techniques are well known, thus it would have been obvious to
11 combine the references to achieve an equivalent.

12 As noted above with respect to the rejection of Claim 1, the combination of Adams and
13 Hamilton is inappropriate, because the function of a conductive elastomer evaluation circuit is to
14 enhance realism, and according to Hamilton's mode of operation realism is not the goal (in fact,
15 Hamilton intentionally provides an un-realistic model to enable nerve impulses to be more readily
16 visualized). MPEP 2143.01 specifically provides that "if the proposed modification or combination of
17 the prior art would change the principle of operation of the prior art invention being modified, then
18 the teachings of the references are not sufficient to render the claims prima facie obvious." Thus, the
19 combination of Hamilton and Adams is inappropriate.

20 Accordingly, the rejection of independent Claim 79 under 35 U.S.C. § 103(a) should be
21 withdrawn because the cited art does not teach or suggest all of the recitation of Claim 79.

22 Since dependent claims inherently include all of the recitation of the independent claims from
23 which they ultimately depend, for at least the same reasons as noted above in connection with
24 independent Claim 79, the rejection of dependent Claims 80 and 81 should also be withdrawn.

25 Patentability of Independent Claim 96

26 Claim 96 as amended specifically recites a medical training model including a generally
27 planar conductive elastomer based evaluation circuit disposed between an exterior surface and a
28 target portion, such that an incision through the conductive elastomer based evaluation circuit is
29 required in order to open the evaluation circuit.

1 The Examiner has rejected Claim 96 based on a combination of Adams and Hamilton.
2 Applicant respectfully submits that this rejection is not clear as neither reference teaches or
3 suggests a model configured to reach a target portion by performing an incision on a conductive
4 elastomer based evaluation circuit.

5 Nicholls however does disclose an exterior surface, a target (a nerve), and concentric layers of
6 conductive elastomer based evaluation circuits that must be pierced by a needle to reach the target (a
7 center of the nerve bundle). As amended, Claim 96 distinguishes over Nicholls because the inner
8 (i.e., underneath the outer layer) conductive elastomer based evaluation circuit is planar, and as
9 discussed in detail above Nicholls' inner conductive elastomer based evaluation circuits ARE NOT
10 planar.

11 Accordingly, the rejection of independent Claim 96 under 35 U.S.C. § 103(a) should be
12 withdrawn because the cited art does not teach or suggest all of the recitation of Claim 96.

13 Patentability of Independent Claim 99

14 Claim 99 specifically recites a medical training model including a conductive elastomer
15 evaluation circuit with a switch disposed within a simulated physiological structure, where the switch
16 is either capacitance switch or an RF switch.

17 The Examiner asserts that Adams discloses a medical training model including a conductive
18 elastomer evaluation circuit that acts as a switch, and that D'Antonio discloses a capacitance switch,
19 and that it would have been obvious to incorporate D'Antonio's switch into Adams' structure.

20 Applicant respectfully submits that Adams' model does not in fact include a switch. Adams
21 does include a layer separating two conductors that changes state in response to pressure. While it is
22 true that the layer is responsible for "switching" the circuit defined by the two non-physically
23 connected conductors, it is poorly reasoned to suggest that Adams' pressure sensitive conductive
24 polymer could be replaced by the switch disclosed by D'Antonio.

25 If such a substitution were made, then the breast model disclosed by Adams would no longer
26 function properly. D'Antonio's switch does not respond to pressure changes, and is therefore not
27 suitable for use in Adams' breast model, as it would render Adams' breast model unsuitable for its
28 intended purpose.
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1 MPEP 2143.01 specifically provides that “if proposed modification would render the prior art
2 invention being modified unsatisfactory for its intended purpose, then there is no suggestion or
3 motivation to make the proposed modification.”

4 Because the proposed modification would prevent Adams’ breast model from tracking pressure
5 changes while a student manipulated the breast model, the breast model would no longer be suited to its
6 intended purpose. Thus, the proposed combination is invalid per USPTO stated policies and
7 procedures.

8 Accordingly, the rejection of independent Claim 99 under 35 U.S.C. § 103(a) should be
9 withdrawn.

10 Patentability of Independent Claim 100

11 Claim 100 specifically recites a medical training model including a conductive elastomer
12 evaluation circuit in which a current is induced by a tool without any contact between the tool and
13 circuit.

14 The Examiner asserts that Adams discloses a medical training model including a conductive
15 elastomer evaluation circuit, and that Damadian discloses a medical model in which a tool induces a
16 current in a circuit not made from a conductive elastomer. The Examiner asserts it would have been
17 obvious to combine the references to achieve an equivalent.

18 With respect to modifying Adams in view of Damadian, such a modification would render
19 Adams’ breast model unsuitable for its intended purpose. Note that Adams’ breast model is
20 specifically intended for the purpose of training people to manually detect breast cancer in a model of
21 a human female breast. To add the capability of being able to use a tool to induce a current in the
22 circuit, during this manual exam, would render Adams unsatisfactory for its intended purpose, which
23 is train people to apply pressure with their hands to a woman’s breast in order to feel for tumors.

24 With respect to modifying Damadian in view of Adams, such a modification would
25 unnecessarily complicate Damadian’s design without providing a benefit. Such a modification is
26 illogical, and can only be based on hindsight. Note the function of a conductive elastomer evaluation
27 circuit is to enhance the realism of a simulated physiological structure. Damadian strives to promote
28 realism, but only with respect to images displayed on a monitor. Damadian’s principle of operation
29 is to use images from REAL patients, and to display an appropriate image based on the positions of a
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1 training model and simulated instruments. It is irrelevant that the simulated physiological structure
2 look or feel real, as the student is looking at REAL images on the monitor anyway.

3 Therefore, the suggested combination is invalid. Accordingly, the rejection of independent
4 Claim 100 under 35 U.S.C. § 103(a) should be withdrawn.

5 Conclusion

6 In consideration of the amendment to the claims and the Remarks set forth above, it is
7 applicant's position that all claims in the current application are patentable over the art of record.
8 The Examiner is thus requested to pass this case to issue without further delay. In the event that any
9 other issues remain, the Examiner is invited to telephone applicant's attorney at the number listed
10 below.

11 Respectfully submitted,

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